Remarks

Claims 7 and 9-16 are in the case. All claims stand rejected. Reconsideration of the rejections is respectfully requested for the reasons set forth below.

Claim Rejections - 35 USC § 112

Claims 11 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant requests consideration of the foregoing amendments to claims 11 and 15, which are believed to address the issues noted by the Examiner.

Claim Rejections - 35 USC § 103

Prior to discussing each ground of rejection, applicant will summarize general positions that are applicable to applicant's traversal of each rejection under 35 U.S.C. § 103(a).

All of the obviousness rejections are based on the position that injectability and paste like properties are implicit in the teachings of Randolph. However, this does not establish that the teachings of Randolph provide an injectable bone graft material having the characteristics of the claimed invention. Applicant owns the Randolph reference, and the research that led to the claimed invention resulted from efforts to improve on prior art calcium sulfate bone graft materials, such as those of Randolph. Applicant's specification identifies the following problems with prior art injectable calcium sulfate bone graft materials:

> [I]mprovements are desirable relating to working time (the time period available in which the bone graft material can be implanted in the body), injectability (the relative force required to easily inject the bone graft material through associated instrumentation using hand and/or thumb force), the set or cure time relative to

> compressive strength, the compressive strength achieved one hour after injection and the compressive strength achieved 24 hours after injection. Calcium sulfate hemihydrate for use as bone graft materials have, in the past, been made using hydrothermal processes where calcium sulfate dihydrate is boiled in a reaction vessel under greater than atmospheric pressure and result in a structure which requires an undesirable amount of water for hydration."

Applicant solved the foregoing drawbacks of prior art calcium sulfate bone graft materials by identifying a particular type of calcium sulfate, the unexpected properties of which are described at ¶¶13-14 of applicant's published application as follows:

> [0013] As noted above the calcium sulfate hemihydrate has low water-carrying capacity and is formed of thick, stubby rod-like crystals, as disclosed in U.S. Pat. No. 2,616,789. Such calcium sulfate hemihydrate has not been used, prior to the present invention, as a bone graft or substitute material. Unexpectedly, such calcium sulfate hemihydrate allows optimizing of action times and compressive strength as well as being resorbable, that is absorbable in the body within a time required to permit bone defect healing.
>
> [0014] In accordance with the present invention, after mixing, a working time of 5 minutes or greater, depending on the amount of diluent or accelerant added, can be achieved to permit the injectable resorbable bone graft paste to be loaded into the syringe and to be injected into the bone, e.g. via the syringe and pre-placed needle. At the same time, the injectable resorbable bone graft material sets or cures quickly in the body to provide improved compressive strengths from prior art bone graft materials.

Thus, the claimed invention is directed to the use of a particular type of calcium sulfate which provides what applicant considers to be unexpected properties and benefits when injecting calcium sulfate bone graft materials. The claims have been amended such that they are more specifically directed to the use of this particular type of calcium sulfate, together with particular properties conferred by the use of this material.

While the Examiner points out that the Murray and Constantz references teach various properties of injectable bone graft materials, such as injectability, set time, and hardness, these references are directed to the use of calcium phosphate based bone graft materials. To those of skill in the art of bone grafts, this is an important distinction. Calcium sulfate and calcium

phosphate have very different properties when used as bone graft materials. In particular, calcium phosphate yields a much harder bone graft, but also takes much longer to be resorbed by the body, which can impede the formation of new bone. A unique property of the claimed methods is the ability to deliver by injection a calcium sulfate bone graft that sets to a hardness that is unexpectedly higher than that of prior art calcium sulfate bone grafts. Combining calcium phosphate materials, such as those of the cited Murray and Constantz references, with the type of calcium sulfate used in the claimed invention would not lead to the claimed methods, but in fact to a graft having different properties. In *KSR*, the Supreme Court cautioned that the obviousness analysis must be made explicit. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741, 167 L.Ed.2d 705, 82 USPQ.2d 1385 (2007), citing *In re Kahn,* 441 F.3d 977, 988 (C.A.Fed.2006). While the Examiner has set out a thorough discussion of each ground of rejection, applicant requests clarification as to whether the Examiner is taking the position that the various cited references can be combined to provide an injectable composition having the characteristics of the claimed methods, and if so, evidence for such a position.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632). The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner interprets Constantz et al. as teaching injecting a similar product (7:30-35). The Examiner concludes that Randolph et al. and Constantz et al. are combinable because they are from the same field of endeavor; namely, bone implant materials. The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al, with the injection

and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

As discussed above, a combination of the calcium phosphate material of Constantz and the calcium sulfate of Randolph would not result in the claimed invention, but in fact a different composition that would not achieve the objectives of the claimed methods (low water demand; injectability for a short but suitable period prior to setting; higher than expected setting strengths for a calcium sulfate bone graft; the relatively rapid resorption properties of calcium sulfate bone grafts). Applicant requests clarification and reconsideration of the grounds of rejection in view of the amendments, which are more particularly directed to particular properties of the preferred embodiment. If the Examiner's position is that the compositions of Randolph and Constantz can be combined to provide an injectable composition having the characteristics of the claimed invention, then applicant respectfully requests authority for the proposed result of such a combination, which would be surprising, and would not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To maintain the ground of rejection, applicant suggests that the Commissioner must provide documentary evidence. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) as evidenced by Tiemann et al. Applicant disagrees with the interpretation and reliance on the Tiemann et al. article. The Examiner takes the position that calcium sulfate hemihydrate inherently forms thick,

stubby, rod like crystals, as is evidenced by Tiemann et al. (page 1267). On the contrary, Tiemann et al. discusses a highly unusual situation in which an underwater creature manages to form crystals of calcium sulfate hemihydrate in an aqueous environment. See Tiemann et al. p. 1266 ("To our surprise we found that the statoliths consist of calcium sulfate hemihydrate (CaSO4 · 0.5 H2O) and *not* of the dehydrate ($CaSO_4 \cdot 2H_2O$), ie. gypsum (Fig.4), as we had expected."(emphasis original)). Calcium sulfate does not inherently form thick, stubby, rod like crystals, and Tiemann et al. does not support such a conclusion.

The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner takes the position that Constantz et al. teaches injecting a similar product (7:30-35). The Examiner concludes that Randolph et al. and Constantz are combinable because they are from the same field of endeavor, namely, bone implant materials. The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape.

As discussed above, a combination of the calcium phosphate material of Constantz and the calcium sulfate of Randolph would not result in the claimed invention, but in fact a different composition that would not achieve the objectives of the claimed methods (low water demand; injectability for a short but suitable period prior to setting; higher than expected setting strengths for a calcium sulfate bone graft; the relatively rapid resorption properties of calcium sulfate bone grafts). Applicant requests clarification and reconsideration of the grounds of rejection in view of the amendments, which are more particularly directed to particular properties of the preferred embodiment. If the Examiner's position is that the compositions of Randolph and Constantz can

be combined to provide an injectable composition having the characteristics of the claimed invention, then applicant respectfully requests authority for the proposed result of such a combination, which would be surprising, and would not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To maintain the ground of rejection, applicant suggests that the Commissioner must provide documentary evidence. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test).

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Constantz (U.S. Patent No. 6,375,935).The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner takes the position that Constantz et al. teaches injecting a similar product (7:30-35). The Examiner concludes that Randolph et al. and Constantz et al. are combinable because they are from the same field of endeavor, namely, bone implant materials. The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and that one would have been motivated to do so in order to fill a bone defect with an obscure shape. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength above 15 MPa within one hour, 45-49 MPa within one hour, or over 50 MPa within one hour after injection. However, the Examiner takes the position that Constantz teaches a similar material which sets in an in vivo fluid environment in 4-10 minutes into a solid

having a compressive strength of at least about 40-70 Mpa (Claim 9). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz, and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength above 15 MPa within one hour after injecting. However, the Examiner takes the position that Constantz implicitly teaches this limitation through testing in an in-vivo fluid environment (7:30-47 and Claim 9). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz, and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

As discussed above, a combination of the calcium phosphate material of Constantz and the calcium sulfate of Randolph would not result in the claimed invention, but in fact a different composition that would not achieve the objectives of the claimed methods (low water demand; injectability for a short but suitable period prior to setting; higher than expected setting strengths for a calcium sulfate bone graft; the relatively rapid resorption properties of calcium sulfate bone grafts). Applicant requests clarification and reconsideration of the grounds of rejection in view of the amendments, which are more particularly directed to particular properties of the preferred embodiment. As with the previous grounds of rejection, if the Examiner's position is that the compositions of Randolph and the Constantz references can be combined to provide an injectable composition having the characteristics of the claimed invention, then applicant

respectfully requests authority for the proposed result of such a combination, which would be surprising, and would not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To maintain the ground of rejection, applicant suggests that the Commissioner must provide documentary evidence. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test).

Claims 9-11 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No.5,820,632). The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner takes the position that Constantz et al. teaches injecting a similar product (7:30-35). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone: defect with an obscure shape. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength above 15 MPa within one hour, 45-49 MPa within one hour, or over 50 MPa within one hour after injection. However, the Examiner takes the position that Constantz et al. implicitly teaches these limitations considering that time to one half of the compressive strength may be fewer than 3 hours, and the optimal compressive strength is greater than 110 MPa (8:40-50). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the

compressive strength and setting time taught by Constantz et al., and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength above 15 MPa within one hour, 45-49 MPa within one hour, or over 50 MPa within one hour after injection. However, the Examiner takes the position that Constantz et al. implicitly teaches this limitation through testing in an in-vivo fluid environment (9:15-25). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz et al., and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

For the same reasons discussed above with regard to the first ground of rejection of claims 9-11, which are incorporated by reference, applicant traverses, and requests clarification and reconsideration.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Constantz (U.S. Patent No. 6,375,935). The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner takes the position that Constantz et al. teaches injecting a similar product (7:30-35). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and that one would have been motivated to do so in order to fill a

bone defect with an obscure shape. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 6 MPa within 20 minutes after injection. However, the Examiner interprets Constantz as teaching a similar material which sets in an in vivo fluid environment in 4-10 minutes into a solid having a compressive strength of at least about 40-70 Mpa (Claim 9). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz, and that one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 6 MPa within 20 minutes after injecting. However, the Examiner interprets Constantz as implicitly teaching this limitation through testing in an in-vivo fluid environment (7:30-47 and Claim 9). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression .strength testing in an in-vivo environment taught by Constantz, and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

As discussed above, a combination of the calcium phosphate material of Constantz and the calcium sulfate of Randolph would not result in the claimed invention, but in fact a different composition that would not achieve the objectives of the claimed methods (low water demand; injectability for a short but suitable period prior to setting; higher than expected setting strengths for a calcium sulfate bone graft; the relatively rapid resorption properties of calcium sulfate bone grafts). Applicant requests clarification and reconsideration of the grounds of rejection in view of

the amendments, which are more particularly directed to particular properties of the preferred embodiment. As with the previous grounds of rejection, if the Examiner's position is that the compositions of Randolph and Constantz can be combined to provide an injectable composition having the characteristics of the claimed invention, then applicant respectfully requests authority for the proposed result of such a combination, which would be surprising, and would not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To maintain the ground of rejection, applicant suggests that the Commissioner must provide documentary evidence. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test).

Claim 12 is also rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632). The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner interprets Constantz et al. as teaching injecting a similar product (7:30-35). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 6 MPa within 20 minutes after injection. However, the Examiner interprets Constantz et al. as implicitly teaching this limitation (10:15-25) (see also MPEP 2144.05 and 2131.03). The Examiner

concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz et al., and one would have been motivated to do so in order to provide quicker in vivo setting, which is more convenient for doctors and patients. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 6 MPa within 20 minutes after injecting. However, the Examiner takes the position that Constantz et al. implicitly teaches this limitation through testing in an in-vivo fluid environment (9:15-25). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz et al., and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

For the same reasons discussed above with regard to the first grounds of rejection of claim 12, which are incorporated by reference, applicant traverses, and requests clarification and reconsideration.

Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Constantz (U.S. Patent No. 6,375,935). The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner interprets Constantz et al. as teaching injecting a similar product (7:30-35). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in

situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 35 MPa or about 55 MPa within 24 hours after injection. However, the Examiner interprets Constantz as teaching a similar material which sets in an in vivo fluid environment having a compressive strength well in excess of 50 MPa at one day after immersion in distilled water (7:35-47) (see also MPEP 2144.05 and 2131.03). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz, and that one would have been motivated to do so in order to provide quicker in vivo setting. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 35 MPa or about 55 MPa within 24 hours after injecting. However, the Examiner interprets Constantz as implicitly teaching this limitation through testing in an in-vivo fluid environment (7:30-47). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz, and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

As discussed above, a combination of the calcium phosphate material of Constantz and the calcium sulfate of Randolph would not result in the claimed invention, but in fact a different composition that would not achieve the objectives of the claimed methods (low water demand; injectability for a short but suitable period prior to setting; higher than expected setting strengths for a calcium sulfate bone graft; the relatively rapid resorption properties of calcium sulfate bone

grafts). Applicant requests clarification and reconsideration of the grounds of rejection in view of the amendments, which are more particularly directed to particular properties of the preferred embodiment. As with the previous grounds of rejection, if the Examiner's position is that the compositions of Randolph and Constantz can be combined to provide an injectable composition having the characteristics of the claimed invention, then applicant respectfully requests authority for the proposed result of such a combination, which would be surprising, and would not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To maintain the ground of rejection, applicant suggests that the Commissioner must provide documentary evidence. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test).

Claims 13 and 14 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632). The Examiner admits that Randolph et al. does not teach the step of injecting the paste directly into a bone defect. However, the Examiner interprets Constantz et al. as teaching injecting a similar product (7:30-35). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the mixture/paste of Randolph et al. with the injection and in situ curing of Constantz et al., and one would have been motivated to do so in order to fill a bone defect with an obscure shape. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 35 MPa or about 55 MPa within 24 hours after injection. However, Constantz et al.

teaches a similar material which sets in an in vivo fluid environment having a compressive strength of 110 MPa in less than 8 hours (8:40-50) (see also MPEP 2144.05 and 2131.03). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength and setting time taught by Constantz et aI., and one would have been motivated to do so in order to provide quicker in vivo setting. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at least 35 MPa or about 55 MPa within 24 hours after injecting. However, the Examiner interprets Constantz et al. as implicitly teaching this limitation through testing in an in-vivo fluid environment (9:15-25). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in an in-vivo environment taught by Constantz et al., and one would have been motivated to do so in order to determine the amount of time that the patient would need to be immobile.

For the same reasons discussed above with regard to the first grounds of rejection of claims 13-14, which are incorporated by reference, applicant traverses, and requests clarification and reconsideration.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randolph et al. (U.S. Patent No. 5,614,206) in view of Constantz et al. (U.S. Patent No. 5,820,632) and Murray (U.S. Patent No. 4,778,834).

The Examiner admits that Randolph et al. does not teach that the material has a compressive strength of about 88 MPa orexceeding 106 MPa within 24 hours after mixing in a

dry testing environment. However, the Examiner interprets Murray as teaching a similar product with dry testing values that obviate these ranges (Table 2 and 13:20-25) (see also MPEP 2144.05 and 2131.03). The Examiner concludes that Randolph et al. and Murray are combinable because they are from the same field of endeavor, namely, bone implant materials. The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the bone material taught by Randolph et al. with the compressive strength taught by Murray, and one would have been motivated to do so in order to provide a bone implant which best mimics the true compressive strength of natural bone. The Examiner further admits that Randolph et al. does not teach that the material has a compressive strength of at about 88 MPa or exceeding 106 MPa within 24 hours after mixing in a dry testing environment. However, the Examiner interprets Murray as teaching a dry testing environment (13:20-25). The Examiner concludes that at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the testing of the material taught by Randolph et al. with the compression strength testing in a dry environment taught by Murray, and that one would have been motivated to do so in order to obtain data for comparing the product's mechanical qualities to those of potential competitors.

As discussed above, a combination of the calcium phosphate material of Murray and the calcium sulfate of Randolph would not result in the claimed invention, but in fact a different composition that would not achieve the objectives of the claimed methods (low water demand; injectability for a short but suitable period prior to setting; higher than expected setting strengths for a calcium sulfate bone graft; the relatively rapid resorption properties of calcium sulfate bone grafts). Applicant requests clarification and reconsideration of the grounds of rejection in view of the amendments, which are more particularly directed to particular properties of the preferred

embodiment. As with the previous grounds of rejection, if the Examiner's position is that the compositions of Randolph and Constantz can be combined to provide an injectable composition having the characteristics of the claimed invention, then applicant respectfully requests authority for the proposed result of such a combination, which would be surprising, and would not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. To maintain the ground of rejection, applicant suggests that the Commissioner must provide documentary evidence. See 37 CFR 1.104(c)(2). See also Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test).

Conclusion

Applicant suggests that claims 7 and 9-16 are in condition for allowance. This response has been filed with a petition and fee for a one month extension of time. It is believed that no further extension of time is therefore required, but if an extension is required, applicant hereby requests an appropriate extension of time. It is further believed that no additional fees are due, but if any fees or credits are due, the Commissioner is authorized to charge or deposit them to Deposit Account No. 502795.

Respectfully submitted,

/Shawn D. Sentilles/

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